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INCY - Q4 2013 Incyte Corporation Earnings Conference Call

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PRESENTATION

Operator

Greetings, ladies and gentlemen, and welcome to the Incyte Corporation fourth-quarter and year-end 2013 earnings call.

(Operator Instructions)

As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Ms. Pamela Murphy, Vice President, Investor Relations and Communications. Thank you, Ms. Murphy, you may begin.

Pamela Murphy - *Incyte Corporation - VP of IR and Corporate Communications*

Good morning, and, again, welcome to Incyte's fourth-quarter and year-end conference call. On the call today is Herve Hoppenot, who, as most of you know, joined Incyte last month as President and Chief Executive Officer. Also on the call today are Jim Daly, who leads our commercial team; Dave Hastings, our Chief Financial Officer; Rich Levy, who directs drug development; and Reid Huber, who heads Discovery Biology.

Herve will begin with a brief overview of the quarter and Jim follow with an update on Jakafi, and Rich will highlight progress made in our lead clinical programs. Dave will then describe our fourth-quarter financial results and 2014 financial guidance. After our formal remarks, we will open up the call for Q&A.

Before beginning we would like to remind you that some of the statements made during the call today are forward-looking statements, including statements regarding our expectations for the commercialization of Jakafi, our development plans for Jakafi and other indications and for other compounds in our pipeline, and our 2014 financial guidance.

These forward-looking statements are subject to a number of risks and uncertainties that may cause our actual results to differ materially, including those described in our 10-Q for the quarter ended September 30, 2013, and from time to time in our SEC documents. Herve?

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you, Pam, and thank you all for attending this call. First, I'll just say I'm very excited of joining the Incyte team. And I want to congratulate and thank Paul Friedman for building such a company that is in a great position to continue to develop a broad portfolio of products to significantly improve patient outcomes.

Now, looking back at 2013, we delivered a very strong and sustained sales growth for Jakafi in myelofibrosis and exceeded the revenue guidance. The big news, obviously, for patients was at ASCO when we updated our survivor data and suggested that Jakafi can slow progression of disease and prolong the life of patients with myelofibrosis.

We also saw data from RECAP, our Phase II trial of ruxolitinib in pancreatic cancer, and these data are encouraging for patients, not only with pancreatic cancer but also with other solid tumors. Additionally, we developed our pipeline and advanced a number of projects. And, during the year, we also restructured and strengthened the balance sheet, which gives us the ability to reinvest and grow our pipeline and continue to discover and develop new drugs.

Now, looking forward to the future, starting obviously now in 2014, first, we believe we will see continued growth in myelofibrosis, which you can see reflected in our net product guidance for 2014 in the range of $315 million to $335 million. Now, remember myelofibrosis is just the beginning for Jakafi.

We look forward for expanding to other indications, first in the PV where we expect to file sNDA in the first half of the year and are getting our team ready for successful launch. And next, solid tumor, where we are planning two Phase III studies in pancreatic cancer and Phase II trials in breast cancer, colon cancer, and non-small cell lung cancer.

Our lead JAK1 inhibitor also has a potential in treating solid tumor and we are testing it first in non-small lung cancer. We are also obviously excited about the potential of our IDO program. Just last week we announced that the deal with Merck to combine our IDO1 inhibitor with their anti-PD-1 immunotherapy in non-small lung cancer where we would be starting studies during the year. And we intend to establish other collaborations to show that our IDO1 inhibitor can do in various types of cancer.

Another combination we are working on is one where we are combining two of our own compounds, the PI3 kinase-delta inhibitor and the JAK1 inhibitor, first in B-lymphoid malignancies. Now, that's for the oncology portfolio.

Now we also, where we have obviously a very growing portfolio, but we are not forgetting the potential revenue stream that we have from our compounds in inflammation where our alliance with Lilly could deliver significant value for baricitinib, our second JAK1/JAK2 inhibitor, and we are starting Phase II trials for our second JAK1 inhibitor in rheumatoid arthritis in the first half of the year.

You see we have opportunities there to have an approach where we will have two distinct JAK1 inhibitor, one in oncology and one in inflammation, just as we did with ruxolitinib and baricitinib. Now, Jim will provide more details around our commercialization of Jakafi.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Thank you, Herve, and good morning, everyone. Our growth strategy for Jakafi -- to add new patients at a healthy consistent rate while keeping patients on treatment longer -- yielded continued solid results in the fourth quarter, as evidenced by the $72.9 million in net product revenues. I'd like to thank our Incyte colleagues for their tireless efforts in educating physicians about the optimal use of Jakafi to benefit patients with intermediate or high-risk myelofibrosis.

In terms of quarter-over-quarter growth, net sales grew 21% with the following components of growth: underlying demand, as measured by bottles dispensed to patients, grew by 7%; net price accounted for 7 points of growth; and inventory accounted for 7 points of growth.

We exited the fourth quarter with inventory levels at the high end of our normal range of 3 to 3.5 weeks. The dollar value increase in inventory between the third and the fourth quarters was approximately $4 million, a portion of which we expect to reduce in the first quarter.

Our full-year 2013 net sales of $235.4 million reflects 73% growth over 2012 net sales of $136 million. Our fourth-quarter performance was consistent with our expectations for steady growth in underlying demand, which we saw throughout 2013.

New patient starts remained consistent with previous quarters and the number of prescribers has continued to increase. Through the fourth quarter, nearly 60% of our target prescribers have prescribed Jakafi at least once and 36% have prescribed for two or more patients. One-third of new patients come from new prescribers and two-thirds come from previous prescribers, reflecting a gradual shift to existing prescribers relative to prior quarters.

We continue to see increasing use of lower-dosage strengths, which is driven by physicians individualizing treatment. In the fourth quarter, 5- and 10-milligram strengths represented nearly 50% of dispensed bottles, up from 43% during the same period last year and slightly up from the third quarter this year. This reflects appropriate patients starting on lower-dosage strengths or patients titrating downward as necessary.

Looking at 2014, we continue to believe that the total US population of patients with myelofibrosis is between 16,000 and 18,500. Approximately 80% to 90% of patients diagnosed with MF are intermediate or high risk. We believe that a significant proportion of patients who may benefit from Jakafi still remain untreated, which provides an opportunity for future growth.

From a physician perspective, we see an opportunity to increase breadth of prescribing while also increasing depth of prescribing. Our expanded sales force will enable us to reach more physicians, with greater frequency, in 2014.

We continue to experience a favorable reimbursement environment. The vast majority of payers manage Jakafi consistent with the label and physicians are able to successfully manage most prior authorizations that exist. Financial assistance is provided by our IncyteCARES program or through independent foundations.

Through scientific channels, emerging data on overall survival are emphasizing the medical imperative to treat patients earlier in the course of the disease. We hope to have certain overall survival data reflected in the product package insert, as a result of a labeling update expected in the third quarter.

Our guidance of $315 million to $335 million in net product revenues in 2014 reflects year-over-year growth between 34% and 42%, driven by new patient starts and continued improvement in persistency. Our guidance assumes no meaningful contribution to revenues in 2014 from an FDA-approved indication in PV.

Based on our market research, we continue to expect -- assuming FDA approval -- the PV indication will make a substantial contribution to Jakafi sales in 2015. The addressable patient population for PV is larger than that of MF, and the length of treatment of PV is likely to be longer than MF.

Based upon claims data, there are at least 100,000 PV patients diagnosed and treated in the US. 60% of them are currently on HU or previously on HU but discontinued because of side effects or lack of efficacy. We estimate that approximately 25,000 of these patients are resistant to, or intolerant of, HU and suffer from uncontrolled PV while on best-available therapies.

A primary treatment goal for PV patients -- to consistently reduce and maintain hematocrit levels below 45% -- was achieved in the Jakafi Phase II study in almost all patients who were resistant to, or intolerant of, HU. Patients also experienced reductions in spleen size and improvements in debilitating symptoms.

These uncontrolled PV patients have significant unmet needs and reflect a major commercial opportunity for Jakafi. We are taking all appropriate steps to help ensure that we will maximize the opportunity in front of us with PV.

We've always said that MPNs are just the beginning. We have a deep pipeline of novel molecules and innovative programs that represent an exceptional opportunity to make a difference for patients. To discuss this in more detail, I'll now turn it over to Rich.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Thanks, Jim. Our development efforts with Jakafi in myeloproliferative neoplasms continue to advance on several fronts. With respect to intermediate or high-risk myelofibrosis, we submitted an sNDA early in the fourth quarter for inclusion of certain survival data in our label and we expect to have a response from the agency by the third quarter.

Additionally, our Phase III registration study for polycythemia vera that is being conducted under an SPA will read out soon. We expect to have top-line data to announce in March or April and then to submit the sNDA in June for the treatment of PV patients resistant to, or intolerant of, hydroxyurea. As we said in our third-quarter call, the FDA granted fast-track status for this indication and, assuming a six-month review, we would potentially have approval by year end.

Finally, we expect to submit full results from the symptom-improvement study in patients with PV -- a study called RELIEF -- for presentation at ASH, which should be around the time of our potential PV launch, after which we intend to submit an sNDA labeling update for the symptomatic benefit.

I'll turn next to our development efforts focusing on JAK inhibition in solid tumors. During the last quarterly call, we outlined results from RECAP, the Phase II double-blind placebo-controlled study of ruxolitinib plus capecitabine versus capecitabine alone in second-line pancreatic cancer.

These results showed a hazard ratio for overall survival of 0.47, favoring the ruxolitinib arm in our prospectively defined subgroup of patients harboring evidence of tumor-induced inflammation and, therefore, potentially more likely to benefit from JAK inhibition. For competitive reasons we're not disclosing the details around the subgroup at this time.

However, based on these very encouraging results, as well as the abundance of data supporting the potential utility of this subgroup in defining higher-risk patient population in many other solid tumor histologies, we believe that JAK inhibition represents a new treatment approach for patients suffering not only from pancreatic cancer, but also possibly many other solid tumors. It is an important therapeutic opportunity for JAK inhibition as this subgroup can represent 30% to 75% of patients, depending on the tumor type and line of therapy.

Published literature describing the biology of tumor-induced inflammation and our own preclinical data suggest that selective JAK1 inhibition may be similarly effective relative to our dual JAK1/JAK2 inhibitor ruxolitinib when it comes to this approach to treatment. By virtue of the bone marrow-sparing properties of selective JAK1 therapy, this provides its own spectrum of opportunities, particularly in patients with whom myelosuppressive chemotherapy is warranted and in whom concurrent ruxolitinib therapy may, therefore, be less well tolerated.

We are beginning this development program with two double-blind placebo-controlled Phase II studies in patients with non-small cell lung cancer. These studies will evaluate 39110 on a background of two different chemotherapeutic regimens, and we expect these data, as well as emerging data with ruxolitinib, to lay the groundwork for our future development efforts around JAK1 inhibition in solid tumors.

Based on the results of RECAP, the first priority for ruxolitinib is pancreatic cancer. Last August, the FDA granted orphan status for ruxolitinib for the treatment of pancreatic cancer. And, in November, we obtained an agreement on an SPA for a registration trial in second-line setting, evaluating ruxolitinib versus placebo on a background of capecitabine.

Importantly, as part of this SPA, the FDA agreed that enrollment in the Phase III study could be limited to the subgroup identified in RECAP. They also agreed that we did not have to pursue companion diagnostic development efforts in order to identify these patients.

While sufficiently robust results from the single SPA-approved trial could potentially support approval, in order to minimize regulatory risk we are planning a second, nearly identical Phase III trial in this population. Both of these trials will be double-blind and placebo-controlled and are expected to enroll approximately 300 patients each, beginning in the first half of this year. The primary endpoint in each trial is overall survival.

We've also planned three double-blind placebo-controlled Phase II trials of ruxolitinib in non-small lung cancer, breast cancer, and colon cancer, all expected to start in the first half of this year. Each study will focus on the subgroup identified in RECAP and will combine ruxolitinib with therapies that exhibit low to moderate myelosuppressive effects. Again, overall survival will be the primary endpoint in each of these studies.

Looking at our development pipeline beyond JAK inhibition, I'll turn to our IDO1 inhibitor, Incyte24360. We are excited about the potential for this mechanism to provide a meaningful and complementary therapeutic approach in immuno-oncology, a field which is grounded in the scientific literature and well supported by our preclinical data, as well as by early clinical data in combination with the approved anti-CTLA-4 ipilimumab in melanoma. The results of the dose-finding portion of this Phase I/II study have been submitted for presentation at ASCO later this year.

We know that IDO1 inhibitors can provide anti-tumor effects in clinically relevant preclinical models as monotherapy, but it is in combination with checkpoint inhibitors such as anti-CTLA-4 and anti-PD-1 or anti-PD-L1 where significant synergy has been achieved. Based on these preclinical data, it has been our goal to evaluate Incyte24360 in multiple combination regimens across various solid tumor histologies.

Therefore, we are pleased to have just announced, for our first combination study with this novel and particularly exciting checkpoint inhibitor, Merck's anti-PD-1 immunotherapy MK-3475. Under the terms of this agreement, Incyte and Merck will collaborate on and co-fund a Phase I/II study in patients with previously treated metastatic and nonrecurring non-small cell lung cancer, as well as other metastatic cancers.

The trial should begin enrolling patients in the first half of this year. The Phase I portion is expected to be an open-label dose-escalation study to define a recommended regimen of the two combined agents. And the Phase II portion plans to evaluate efficacy and safety of that recommended regimen in a randomized population where all patients receive MK-3475 combined with either 24360 or a placebo. Incyte will conduct the study, though the design and analysis of the study will be done in close collaboration with Merck.

We will continue to let the emerging science drive our development program for 24360. And we anticipate expanding our IDO1 program further this year, focusing on indications and combinations where we believe 24360 may be able to achieve important benefits for patients.

Our broadening hematology-oncology portfolio also gives us opportunities to combine our drugs when preclinical data suggests a combination will have additional clinical benefits. The first such targeted combination being evaluated is with our JAK1 inhibitor 39110 and our PI3K-delta inhibitor 40093, two distinct mechanisms that exhibit synergy in preclinical studies in lymphoma. Last month, we initiated a safety and efficacy study of this combination in patients with B-lymphoid malignancies.

Our discovery group has new programs that are designed to expand and synergize with our clinical development pipeline and we will be prepared to share details around these new oncology programs and their strategic importance to us as they reach clinical development.

With that, I will now turn the call over to Dave, who will explain why we are well positioned to fund our expanding discovery and development programs.

Dave Hastings - *Incyte Corporation - CFO*

Thanks, Rich. Good morning, everybody. I will start today by discussing Q4 results and then review our 2014 guidance.

We ended the year with approximately $509 million in cash and investments. The cash balance reflects the completion of our offering of $750 million of convertible senior notes in the fourth quarter. We used a portion of the net proceeds from this offering to repurchase a total of $117 million aggregate principal amount of our outstanding 2015 convertible senior notes for $500 million in cash. This repurchase resulted in a one-time charge of $17.9 million, recorded in the fourth quarter.

Now, importantly, because of the difference in the conversion price of our 2015 notes compared to the new notes, the resulting net proceeds to the Company of $229 million were minimally dilutive, about 1 million shares on a fully diluted basis per share.

Now moving to Jakafi, we recorded $72.9 million of fourth-quarter and $235.4 million of full-year 2000 (sic -- see press release "2013") net product revenues. Additionally, we recorded $8.4 million in Jakavi product royalties from Novartis for sales outside United States in the fourth quarter and $28.3 million for the year.

Our gross-to-net adjustment for product revenue recognized was $6.5 million, or about 8.2%, for the fourth quarter and $22.1 million, or 8.6%, for the full-year 2013. Our gross-to-net adjustment includes fees to our specialty pharmacies, rebates to government payers, our share of the donut hole for Medicare Part D patients, co-pay assistance to eligible privately insured patients; and any product returns.

We are still using a portion of our prelaunch inventory and, therefore, our cost of goods sold for both the fourth-quarter and full-year 2013 was immaterial as this starting inventory was previously expensed as R&D prior to FDA approval. In terms of our operating expenses, both R&D and SG&A were within our expectations.

Now moving to 2014 guidance. As Herve mentioned, our Jakafi net revenue is expected to be in the range of $315 million to $335 million. In terms of our gross to net adjustment, we expect it to range from 9% to 10% in 2014. Now, because of our portion of the Medicare donut hole, the first quarter's gross-to-net adjustment is historically higher than the rest of the year.

In terms of 2014 contract revenues, we expect $13 million in revenue from the amortization of the upfront payment received under the Lilly collaborative agreement. For milestones, we expect to receive $60 million under the Novartis collaboration, once they receive pricing approval for Jakavi in a third major European country. We expect that total cost of goods sold, as a percentage of net Jakafi sales in 2014, will be about 2%.

Our product gross margins in 2014 will still benefit from the use of previously expensed inventory. Now, steady-state when we are using inventory that has not been previously expensed, we expect cost of goods to be in the range of 4% to 6%, which includes our tiered, low single-digit royalty payments to Novartis on net sales of Jakafi in the US. We begin to pay those once Novartis receives pricing approval for Jakavi in a third major European country.

Now, turning to 2014 R&D expense, we expect it to range from $350 million to $370 million. This includes non-cash stock compensation expense of approximately $30 million to $35 million.

Our increase in R&D expense from 2013 is primarily due to increased development activities related to the expansion of our pipeline, including: the advancement of ruxolitinib in pancreatic cancer and other solid tumors; the advancement of our JAK1 inhibitor in solid tumors; and the development of our IDO1 inhibitor in multiple oncologic indications, in combination with checkpoint inhibitors.

In terms of SG&A expense, we expect it to range from $145 million to $155 million. This includes non-cash stock compensation expense of $28 million to $30 million.

The increase is primarily due to increased sales and marketing investment in support of Jakafi in MF and our prelaunch activities for PV. We expect our interest expense this year to be $48 million including a non-cash charge of $37 million, primarily related to the amortization of a discount on our convertible senior notes.

So, we enter 2014 in a strong financial position to fund our expanding pipeline, $509 million in cash, as well as multiple and increasing sources of cash flow that include net product sales, milestones, and royalties. So, with that, I'll turn the call back over to Herve.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you, Dave. So, it is impressive to see the growing number of products in the pipeline, the growing number of indications that we are pursuing, and the strength of the team in managing the growth of the organization.

And what I see is that we have an opportunity here, obviously, to improve and save lives of people who are relying on us to develop new products for them and also to create and build what could be, in the future, a very successful high-quality, high-growth biopharmaceutical company.

I think that concludes our formal remarks. And, operator, please open the call for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

Liisa Bayko with JMP Securities.

Liisa Bayko - *JMP Securities - Analyst*

Hi, congratulations on a great quarter. Welcome, Herve.

A couple of questions -- for the SPA, can you maybe talk a little bit -- or actually, for the trial I mean, can you maybe talk a little bit about timing of when we might gain some more visibility on the subset that you're going to be focusing on?

And then just to follow-up on that, when you talk about the competitive position and not wanting to tip off competitors, can you maybe talk about, are you speaking about just JAK inhibitors or other mechanisms as well? Thank you

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Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

This is Rich.

Just in terms of the timing, I think the key for us now is really having the best forum to be able to present the whole story. To be able to not just speak to the data, but to be actually able to show slides with data and really put that whole story together.

And we really think that that best opportunity will be an analyst investor meeting probably done in Chicago around the time of ASCO, probably the night of or someday around the time that we actually present the data.

And what we are speaking about is what is the subset of patients that are going to be included or versus those not included in our trials for both JAK1 and ruxolitinib in the solid tumors. We've said that this is related to tumor-induced inflammation and we will put that whole story together in a full way.

I think most of the ideas are already out there. It really comes down to describing what is the specific parameter that we are using. Also with respect to the FDA, as we said, the FDA said we can focus on that group in the Phase III trial. as well as confirmed what we've been saying from the beginning -- that we have no expectation of the need to develop a companion diagnostic, and that's been confirmed in writing in the SPA.

Liisa Bayko - *JMP Securities - Analyst*

Okay, great. Thanks, that's helpful.

And then for IDO, strategically are you thinking of -- does your strategy to leave this open that you'd have the IDO inhibitor that could be partnered with multiple compounds? Or are you thinking more about picking a particular amino therapy to partner with?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Our ideal of this would be a preferred partner for a whole range of immunotherapies including PD-1s, PD-L1s, potentially other emerging targets as well. But at the same time, if one collaborative molecule ends up being a much better combination, we will let the data drive the decisions after that.

Liisa Bayko - *JMP Securities - Analyst*

And then just a technical question. For PV should we be expecting a milestone this year? And maybe what would trigger that? Thanks.

Dave Hastings - *Incyte Corporation - CFO*

So the guidance we've given for milestones, Liisa, just reflect the approval of the pricing for Jakafi in Europe.

Liisa Bayko - *JMP Securities - Analyst*

Okay.

Operator

Matt Roden with UBS.

Matt Roden - *UBS - Analyst*

Congrats to Herve for the new role.

On IDO, with respect to the INCY combo trial, can you give us a sense, Rich, what endpoints you think would best illustrate the added benefit you get with IDO relative to historical controls?

There's been a lot of talk about response rates, which does make sense. I just wonder if you think that we should be also focused on PFS and OS?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Sure. What we're going to be reporting at ASCO is basically the Phase I component of this Phase I/II trial. So everyone is receiving 24360 and ipilimumab, so the comparison is to historical controls.

So when you look at ipilimumab monotherapy, you know that response rates have traditionally been in the 10% to 15% range. We know that progression-free survival with monotherapy in that indication was in the order of 3 months or 100 days, something around those lines.

And survival is, for reasons I'll get into in a second, something that's much harder to compare. So I think the focus will be on response rates and progression-free survival.

The issue with survival is that you really cannot compare one area to the next. In the case of patients who are coming on to this therapy who have not previously received a PD-1 or PD-L1 inhibitor, if they progress they'll often go onto a PD-1 inhibitor and have a prolonged survival as a result of that compared to what was available to patients with the initial ipilimumab studies were done.

So we can report what the survival is; but in terms of a fair comparison, it is really limited to response rates and progression-free survival.

Matt Roden - *UBS - Analyst*

Okay. That's helpful.

In terms of 110 and Jakafi in these solid tumors, can you just maybe speak to how these two can coexist? Is it simply a matter of being able to dose patients where there are myelosuppressive chemotherapy backbones?

Or is there something more there that maybe from the wider therapeutic window with 110, do you think that there might be a way to get greater JAK inhibition, therefore maybe a differentiated efficacy advantage there with 110? Is that on the table at all?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

That's always a theoretical possibility, but the doses of ruxolitinib that were used in the RECAP study were in the order of 15 milligrams twice a day, where we saw in this subgroup a hazard ratio of less than 0.5. So I don't really know that there's room for improvement over what you can do with that sort of dose range of ruxolitinib.

What we get concerned about is when you get into highly myelosuppressive chemotherapy that you would not even be able to provide those levels of ruxolitinib and therefore the comparable levels of JAK inhibition.

So it is conceivable that you could go higher with a JAK1 inhibitor in terms of level of JAK1 inhibition than you did with rux in the RECAP study. But that's not really the rationale for what we are doing.

Right now we have clinical proof of concept with ruxolitinib. We have a lot of models and preclinical data to suggest that JAK1 inhibitors will do the same.

But until we actually demonstrate the clinical proof of concept with the JAK1s, we are not giving up on studying ruxolitinib, particularly in those indications where we believe the drug should be able to be dosed at comparable levels to where it was in RECAP.

Matt Roden - *UBS - Analyst*

That's great. Thanks very much, Rich, for the clarity; and congrats on all the progress.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Thanks.

Operator

Ying Huang with Barclays.

Ying Huang - *Barclays Capital - Analyst*

Thank you for taking my questions, and congratulations on your pipeline advancement.

First of all, you guys announced the collaboration with Merck PD-1 MK-3475 last year. I was just wondering if you could provide any color on what you have supplied to Merck in terms of preclinical data, and does that also include some date you have gleaned from the IDO plus ipilimumab trial?

And then secondly, when are you going to plan to start the Phase II portion of the Yervoy plus your IDO inhibitor trials?

And lastly, just housekeeping question. What should we expect at AACR this year on IDO inhibitor? Thank you.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Let me start.

So Merck as well as some of the other companies that we are speaking with, have seen both our preclinical data and our emerging clinical data. That is not to say that we can define the basis upon which Merck and potentially other companies have decided to move forward with us.

In terms of the Phase II portion of the combination with Yervoy, I think we are getting probably to the point where we're going to study one more cohort. And then probably we will be ready or in a position to start the combination regimen following that.

And because the onset of some of the ipilimumab side effects usually take two to three months to come to fruition, we study patients for a good eight to nine weeks before we actually evaluate the safety in a cohort.

The [cohort] currently enrolling now is now fully enrolled, so I would say it would be a minimum of another three months, probably four, before we might be in a position to start a randomized portion.

And with respect to AACR, I'm going to turn that over to Reid.

Reid Huber - *Incyte Corporation - SVP, Discovery Biology*

What was the question?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

What are we submitting to AACR on IDO-1 inhibition?

Reid Huber - *Incyte Corporation - SVP, Discovery Biology*

Yes, we've previously presented some data at prior meetings.

We'll have an update on our companion diagnostic efforts that are being conducted with Ventana to put ourselves in a position to have a means to potentially select patients. It is not clear if we are going to need that in the clinic or if it is going to enable the clinical development in any way, but we want to make sure that we are in a position to leverage that.

There will also be, I think, pending here soon a publication from Tom Gajewski from the University of Chicago that will describe a lot of his efforts that have been done in collaboration with us exploring the combinatorial activity of IDO inhibition with checkpoint antagonism. That includes with multiple checkpoint inhibitors.

So I would look for those data as well in the coming year.

Ying Huang - *Barclays Capital - Analyst*

Great. Thank you.

Operator

Cory Kasimov with JPMorgan.

Cory Kasimov - *JPMorgan Chase & Co. - Analyst*

I have two more for you on the IDO inhibitor.

If the initial novel combo data warrant advancement, does your agreement with Merck dictate how you'll proceed with later-stage trials? And then I have one other one.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

The agreement is largely around this single trial and does not go into detail about further development depending upon any particular result. Jim is actually more involved with it, if he has anything to add to that.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

I agree with that. At this point, we really don't want to get into the agreement in much detail.

Cory Kasimov - *JPMorgan Chase & Co. - Analyst*

Okay. Understandable.

And then much like Merck, it sounds like you're interested in casting a pretty wide net from a collaborative standpoint. So when thinking about different combinations with your IDO inhibitor, how much preclinical evidence do you need that you are getting an appropriate balance and immune response before pushing ahead into human studies?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I would say that there are times when those data can be important to just advancing our own understanding and creating the confidence that we need to move forward. And I think a good example of that is the work that we've done with Dr. Gajewski in collaboration to study IDO inhibition with checkpoint inhibitors.

I think the more that we understand the basic biology of IDO preclinically, even in a setting like that, we can gain incremental comfort in exploring IDO inhibition with other technologies that may be distinct from checkpoint inhibition, and not necessarily require preclinical gating studies for those.

So I would say that part of this depends on the strength of the preclinical data and its internal consistency, as well as our emerging clinical data and the changes in the therapeutic landscape.

For example, thinking about technologies like vaccine approaches or immune stimulatory agents or even chemo or targeted therapies, our confidence in all of those modalities, I think, is increasing as the immuno-oncology space is itself developing. And we certainly want to be opportunistic and thoughtful as to how we enter into those spaces.

Cory Kasimov - *JPMorgan Chase & Co. - Analyst*

Thank you.

Operator

Brian Abrahams with Wells Fargo Securities.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Congrats on the progress and welcome to Herve.

Can you talk about the rationale for conducting two studies in Jakafi in pancreatic cancer, two Phase IIIs, given that you have an SPA. Maybe talk about the differences between the studies, beyond just I guess timing and geography, and can those be pooled to augment powering?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

When you look at an SPA, an SPA is based on one trial. An SPA is specific to a particular trial, but an SPA is looked at within the context of the Phase III development plan.

So the SPA basically says a design of the first study, which we are calling JANUS1, is acceptable; and which basically means that if the efficacy results are there and there are no safety or benefit risk surprises, that could be the basis of approval.

The traditional guidelines are that it requires two studies to get approval for a new indication or for a new drug; but if one study, particularly on survival, if robust, it can be sufficient.

And that's clearly been acknowledged by FDA. But they did reiterate to us that that study would really need to be robust. And we believe it has an excellent chance of being robust based on the RECAP data.

But it wasn't a difficult thing for us to do a second trial and just diminish our regulatory risk because why would we take more risk than we need to?

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

In terms of differences?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Just take a breath there. I didn't forget the second part of your question. Both studies are going to have an overall endpoint of survival. They are going to enroll the same patient population.

The second trial ,called JANUS2, the main difference is that it will have a few less patients in it. They are both around 300. but it is a little bit less.

Second, that we are adding more patient-reported outcome measures to that study.

Those are not going to be an alpha-controlled endpoint that we do not expect to get labeling for symptomatic benefit based on that study. But we are developing and generating a tool that could potentially be used in a subsequent study to demonstrate symptomatic benefit in that study.

That measure was not ready for prime time at the time we submitted the SPA for JANUS1, but it has been finalized to incorporate those tools. But since that's essentially an exploratory endpoint for that study, it is a minor difference.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Great. That's very helpful.

And then just one quick follow-up. I know in talking about exploiting Jakafi in other solid tumors beyond pancreatic I think you've mentioned the idea of possibly exploring beyond the subgroup tested in RECAP.

Is that something that you are still considering, or are you going to be primarily focused on the subgroup only?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

One of the programs that we are doing -- and I will tell you that it is colon cancer -- with ruxolitinib is a very late line of therapy where there are really very limited options. And that study is being designed so that if the results are quite robust, that study in large Phase II compared to the others, might potentially be a basis of approval without having to go back and do a Phase III.

So therefore, since we have pretty clear data in pancreatic cancer that this basis of restricting enrollment is true in pancreatic cancer, we don't have that data yet in colon cancer. We expect to find it.

So what we are actually doing in that Phase II study is we are enrolling two groups, one who meet the criteria and the group that don't.

But the primary endpoint of the study is still based on the patients that do meet that group. So in that sense, that study is also based on that endpoint. But we are enrolling the other patient population there.

With our studies in non-small-cell and breast cancer, we don't expect that those Phase II studies have the potential to be the basis for registration. So there we are focusing exclusively and only enrolling patients who meet that criterion.

Once we demonstrate, assuming we do demonstrate this in colon cancer in a second solid tumor, that this is a predictive marker for therapeutic success, I don't think we will ever need to do that again in any solid tumor.

Brian Abrahams - *Wells Fargo Securities, LLC - Analyst*

Got it, that's very helpful. Thanks again.

Operator

Salveen Richter with Canaccord Genuity.

Salveen Richter - *Canaccord Genuity - Analyst*

Just wondering if you could just give us some color on why you chose non-small-cell lung cancer for the IDO PD-1 combo trial and what tumors might be up next? And then as well with the JAK1, are you not doing a pancreatic trial anymore? Just curious on that as well.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Okay. So non-small-cell is a focus of the Merck study. We are going to enroll some patients with other things, but the current intent is that the Phase II portion would be focused in non-small-cell. That potentially could still change.

I think that in general, without getting into specific discussions between companies, there's evidence that in non-small-cell cancer PD-1 inhibition is active; but not as active as it is, for example, in melanoma. So therefore, the concept was we want to focus in areas where we already know the PD-1 has some activity; but it's suboptimal, and we want to try to add to it.

And it is our hope, both with Merck and potentially with some of the other collaborations that we are not really prepared to speak to, that we would look at other tumor types as well. But we really cannot get into that until we move forward.

With respect to not doing a JAK1 inhibitor in pancreatic cancer, we are still potentially looking at JAK1 in first-line pancreatic cancer, where the combination is Abraxane and gemcitabine, which is a more highly myelosuppressive chemotherapy where there's a better chance that that could be done with JAK1 than with ruxolitinib. But we are just still going through dose finding there and not prepared to announce anything yet.

For us, we didn't think in the end that it was a good idea for us to do JAK1 inhibition in second-line pancreatic cancer in combination with something like capecitabine again, since we already have that covered. And doing a study there would not directly lead to a new indication.

So we've been focusing in non-small-cell, which would be a larger opportunity should those results be positive.

Salveen Richter - *Canaccord Genuity - Analyst*

Thanks, Rich.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

You're welcome.

Operator

Josh Schimmer with Piper Jaffray.

Josh Schimmer - *Piper Jaffray - Analyst*

Rich, for the IDO inhibitor melanoma study with ipilimumab, can you summarize how many patients have been enrolled so far across the various doses explored?

And coming back to Matt's first question, the speculation amongst investors regarding the response rate for that combination has reached very high levels now. Are you comfortable with those investor expectations? Thanks.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I don't know what the investor expectations are. Can you tell me what they are?

Josh Schimmer - *Piper Jaffray - Analyst*

We hear now 30%, 40% there or higher.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I'm not going to say what the numbers are. All I would say is that it is based on a relatively small end. So there's a lot of uncertainty as to the precision of whatever that number is. So if it was 30% to 40% based on, let's say, 10, that's different than 30% or 40% based on 100.

So I think the thing that I would ask people to remember is that the numbers are not big, but they are enough for us to believe that this is clearly different in terms of at least response rates. And we haven't really spoken about the time to progression or progression-free survival compared to Ipi alone.

I don't remember the exact number of patients that are included here in the abstract. I do believe that there will probably be more data in the actual ASCO presentation than are actually in the abstract. But I would say that in the abstract it is something less than 20, I believe.

Josh Schimmer - *Piper Jaffray - Analyst*

Got it. And should we focus on response rate as well as depth of response? Or is it really response rate overall that has gotten you excited?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I really don't want to try to get into details around depth of response. We know that's been a big topic of presentation, particularly with the PD-1 Ipi combination.

That data is impressive, but our comparison here is really to ipilimumab monotherapy. We are not trying to make any statements about comparison to the combination of Ipi and PD-1s.

Josh Schimmer - *Piper Jaffray - Analyst*

Got it. Thanks so much.

Operator

Navdeep Singh with Goldman Sachs.

Navdeep Singh - *Goldman Sachs - Analyst*

Maybe a question for Herve.

I understand that you've only been at Incyte for a pretty short time. But can you discuss any opportunities you see to improve the business? And are you expecting to make any immediate changes? B6 And then I have a quick follow-up. Thanks.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Immediate changes? No, I must say, I've been here for a month now. And the first comment, the first view about this organization, is about depth and strength because it is a Company that has and is discovering new products with very good productivity.

So that's really the basis of success and value creation in oncology, and that's what Incyte is doing every day.

And it's a team that has a track record of getting things done in a very effective way. And I think the approval of Jakafi, the entire process of developing a first-in-class, getting it approved by FDA, and commercializing it successfully now, is something that is giving the organization a lot of confidence that it can be done again and again.

The second piece is the number of shots on goal that we have. We have a fabulous portfolio of products in the clinic today.

And as you see, we are planning to continue to discover new products for the next few months, and that gives us a very good chance to develop a Company that will be one of the leading biotechs in the future. And that's what I'm really excited about.

Navdeep Singh - *Goldman Sachs - Analyst*

Okay, thanks, and then a question for Rich. Rich, can you please discuss how your IDO1 inhibitor is potentially differentiated from NewLink's IDO1 inhibitor?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

We don't really know all that much about the NewLink IDO1 inhibitor except that on a milligram-per-milligram basis, it's considerably less potent.

That doesn't necessarily translate into a difference in safety or efficacy. But it has the potential that with more milligrams, you may run into some sort of safety things before you can get to the potency. But that truly remains to be seen.

I think the main difference is how far ahead we are in development at this point in time. They are not ready to do the sort of collaborations that we are doing until they generate more data.

It is probably a pretty good molecule. But we are ahead, and we are not really any position to comment on it beyond that.

Navdeep Singh - *Goldman Sachs - Analyst*

Okay, thanks a lot guys.

Operator

Ian Somaiya with Nomura.

Ian Somaiya - *Nomura Asset Management - Analyst*

There's been decades of research pointing to the role of CRP or the prognostic value of CRP in solid tumor. I was hoping to maybe get your thoughts on that front.

And more specifically, is CRP the sort of the end target based on the results in the literature; or is it more of a generalized immune effect?

And maybe just to follow up that thought, or finish that thought, maybe you could speak to the role of JAK-STAT and its potential ability to maybe regulate CRP or just more broadly the inflammatory cascade in cancer.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Let me start, and then I'm going to turn it over to Reid.

We agree that CRP is a marker of certain elements of tumor-induced inflammation, and that's the topic that we are talking about in terms of what we said, tumor-induced inflammation. What we are not saying at this point in time is what is the subgroup and going to do that.

With respect to whether CRP is actually playing a direct role in cancer or is a marker of systemic inflammation, we know there is literature, fairly limited compared to the prognostic literature of CRP, suggesting it may have a direct role in terms of leading to optimization, complement activation and things like that.

But we don't think that you need to hypothesize that CRP is having a direct effect to explain that there probably are other cytokines and inflammatory mediators that are important in terms of both the effect on the tumor, growth, survival, proliferation, as well as on the patient as a whole well. We doubt that it is a single mechanism.

And with respect to JAK-STAT activation, I think that there's more data on some tumor types around JAK-STAT activation than on others. But, no, we are not saying that that is the marker either.

And, Reid, you want to add to that?

Reid Huber - *Incyte Corporation - SVP, Discovery Biology*

Yes, I would just add to that that as we think about tumor-induced inflammation, Ian, it really drives two fundamental processes.

One is a local inflammation in the tumor and its micro environment, and that has been demonstrated across numerous studies. To facilitate tumor growth, it can drive resistance to apoptosis and even can define treatment resistance in some settings. But that's related, but I'd think distinct from systemic inflammation which has been proposed to underlie many of the hallmark features of cancer, including the hypercatabolic state and poor performance status, things like that.

Each of these factors has been shown to have a negative impact on survival, and they are probably each related over time with a progressing malignancy where a local inflammation can reshape and have a disregulated host response.

So I think how you characterize these is an interesting concept. CRP is a way to characterize inflammation, but there are numerous other ways that you can characterize inflammation too.

I think you can look at the published literature and just see how many cytokines, the majority of which interestingly tend to signal through JAK1, can reshape both the local and the systemic inflammatory response.

Ian Somaiya - *Nomura Asset Management - Analyst*

As you get ready for the ASCO Conference and the revelations during analyst meetings, should we assume that given the lack of a companion diagnostic that it is a fairly simple test for a physician to administer?

And that is something that you will be able to readily apply in the marketplace?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Are you asking whether CRP is a fairly simple test? I'm not sure I understand your question.

Ian Somaiya - *Nomura Asset Management - Analyst*

Well, whatever this marker is that you are using, whether it is CRP or let's say a cytokine, a specific cytokine, can you give us a sense of how easy it is to characterize it for the average oncologist? Since you mentioned that there's no need for a companion diagnostic.

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Yes, I would say that the tests are readily available through any lab and well-established.

Ian Somaiya - *Nomura Asset Management - Analyst*

Okay. Maybe a last question on the IDO program.

Maybe a very simple way of thinking about this, but as you look at the data with the PD-1 CTLA-4 combination, we saw fairly high response rates: over 40% if not close to 50%. And I was just curious how should we think about the data set for a IDO plus CTLA-4 combo given the targets or similarities in terms of where the hits on the (inaudible) cascade.

Maybe the question really is, is IDO more similar to CTLA-4? Or is it more similar to PD-1, PD-L1? And how should we think about potential synergies when you look at different combinations?

Reid Huber - *Incyte Corporation - SVP, Discovery Biology*

Ian, this is Reid.

I think it is very difficult to theorize that based on preclinical data. Certainly the mechanism of CTLA-4, as you well know, is quite different than PD-1, PD-L1. And I think that's evidenced not only by differential response rates, but also by differential immuno-related adverse events where CTLA-4 tends to have a much more deleterious, if you will, inflamm-related side effect profile.

To the extent we can study these things preclinically, our data, both with pharmacologic inhibition and genetic knock-out of IDO1, all support the potential for synergy with these mechanisms irrespective of what the intervention is.

And we will ultimately have to rely on the clinical data to point us in the right direction. And I think it is an important aspect of the program to study IDO1 with PD-1s and PD-L1s, given their emerging benefit/risk profile in a lot of different histologies.

And I think that's why we've prioritized that and why we are particularly excited about the Merck collaboration that we just announced.

Ian Somaiya - *Nomura Asset Management - Analyst*

Okay. Thanks for taking my questions, and congratulations on a great quarter.

Herve Hoppenot - *Incyte Corporation - President and CEO*

Thank you.

Operator

Eric Schmidt with Cowen and Company.

Eric Schmidt - *Cowen and Company - Analyst*

Rich, if my friend Josh Schimmer is wrong, and the expectation out there is for 20% to 30% response rates, are you more comfortable with that? I'm just kidding (laughter).

Question on the Merck collaboration. I know you don't want to get into too much detail, but I think it is important for us to understand just how exclusive this is.

In other words, if Merck were to go and develop its own IDO inhibitor internally or find another one out there in the marketplace, would there be anything that prevents them from taking this initial data set and swapping out your IDO inhibitor and moving forward with a combination?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

I'm not going to get into details around the contract. But no one is tied -- just as we are not tied from only working with Merck, they are not tied from working with other molecules it could potentially include.

But terms of the data from this study, there are confidentiality agreements around the data from the study and the use there. But I cannot go into any further detail than that.

Eric Schmidt - *Cowen and Company - Analyst*

Okay, Rich, going back to the question about the Phase III studies on ruxo in pancreatic cancer, Brian's question.

I guess you're doing this little bit differently, doing two smaller Phase IIIs versus what some of your competitors in the pancreatic cancer space have done, one larger Phase III. Could you speak specifically to whether there's a rationale or bias on your part for going in that direction?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

So we have over 90% power, assuming a more conservative hazard ratio than we thought in the Phase II study in the subgroups that we're going to continue to study. For us to do a 900 or what whatever the size of the Abraxane study was, that would be powered to demonstrate a trivial change in survival or the hazard ratio; and that's not what we expect.

We believe that JANUS1, the study that is under the SPA, is sufficiently powered to give not only a P-value of 0.05, but the lower types of P-value's that are needed to potentially support approval based on one study.

And then the second study is about the same size. In the off chance or possibility that the results are not as robust as we expect based on Phase II, then having two studies demonstrating more modest benefits could be sufficient.

Eric Schmidt - *Cowen and Company - Analyst*

Thank you.

Operator

David Friedman with Morgan Stanley.

Unidentified Participant - *Morgan Stanley - Analyst*

Hi, this is [Gorin Kruger] calling in for Dave. Thanks for taking my question. Just a few questions around timing.

Could you provide a little more detail around the enrollment timelines for the pancreatic Phase IIIs? And also, when will we start to see the next solid tumor data points for Jakafi and the JAK1?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Okay. So I'm not going to get specific yet because we really like to see who all the final sites are, how long they take to come up and then how fast they actually enroll compared to the expectations that we have.

So with respect to the time to final data in the JANUS1 and JANUS2 studies, at this point I do not want to be any more predictive than some time in 2016, which is pretty wide spectrum from early 2016 to very late 2016. And, of course, that's just my current estimate.

Those are fully-blinded studies. So there should be no expectation that there would be interim data before that timeframe.

In terms of the Phase II studies, all but one of those Phase II studies has a run in to establish the dose of either ruxolitinib or 39110 in combination with the combinations we are seeing.

And we don't know whether they will have to do one dose level 2, three dose levels. And that makes it hard to predict when we would actually start the randomized portions of the studies.

There is one study where we feel that the dose has already been established. We're moving directly into the randomized portion. And that would most likely be the first study to start to read out.

Of course there, as we go into other tumors besides pancreatic cancer, we are talking about survival that is longer than in pancreatic cancer. And so you might enroll the studies quickly; but until you had a requisite number of deaths, the results would not really read out.

On the Phase IIs I'm really going to reserve any comment on timing of the data other than one of them, unless the survival is actually quite long in both arms, should be ahead of the others.

Unidentified Participant - *Morgan Stanley - Analyst*

Thank you.

Operator

Thomas Wei with Jefferies.

Thomas Wei - *Jefferies & Company - Analyst*

I wanted to ask a couple on IDO and Ipi. Just a reminder of the design of the trial, how many patients are being enrolled per dose cohort? Is it the standard three?

Also, if you remember or just a reminder of how Ipi alone stacks up on something like duration of response/ And then for the JAK1 program, just the rationale for the initial tumor selection here?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

Okay. Let me just make notes here.

So with respect to the ongoing portion of the Ipi study, we are doing more than three patients per cohort because we know that with Ipi alone you're going to get potentially dose-limiting toxicities just from that therapy alone. So if you just did three patients and found one DLT, you might get a false sense.

We are doing, I think it is 6 plus 6; so you do 6 originally, and if you have more than a certain number of DLTs, you expand to 12. I'm not going to get into exactly how many patients and how many times we've had to increase doses, but that's just a general design.

In terms of Ipi duration of response my recollection in melanoma is that it is in the order of about 100 days. And that is something that we will compare within the ASCO abstract and at the presentation.

In terms of the JAK1 tumor selections, we used several factors here in terms of tumor selection both for ruxolitinib and the JAK1 inhibitor. Non-small-cell lung cancer is a place where this same subgroup clearly differentiates prognosis, and we believe that as a result it will lead to differences in the effect of our drug just as it has in pancreatic cancer. It is obviously a large unmet medical need and there are combinations there that made sense to us.

There were plenty of other options. We just have to make some choices here as to how many different studies are we going to do at once. And we think we are taking a moderately-aggressive approach towards looking at a number of Phase II plans here, both with rux and JAK1 in various tumor types.

Thomas Wei - *Jefferies & Company - Analyst*

Is it a signal though that lung cancer might be the next most likely tumor in which this particular selection criteria would be predictive?

Rich Levy - *Incyte Corporation - EVP, Chief Drug Development and Medical Officer*

No. We believe that other than pancreatic cancer, where we have actually a clinical result, the potential here goes across a wide variety of tumor types. So it is in the group of many things that we think could have that sort of benefit.

And then in terms of choosing between them, the size of the potential market, the unmet need, all of those things came into place in terms of picking the first place that we would look.

Thomas Wei - *Jefferies & Company - Analyst*

Great. Thanks.

Operator

Bret Holley with Guggenheim Securities. Bret Holley, your line is live.

Bret Holley - *Guggenheim Securities LLC - Analyst*

Sorry, can you hear me?

Herve Hoppenot - *Incyte Corporation - President and CEO*

Yes, we can now.

Bret Holley - *Guggenheim Securities LLC - Analyst*

Sorry about that. I've got a question for Jim. There's no more questions in the pipeline.

Jim, you mentioned that 60% of your target prescribers are currently prescribing. And I'm wondering how you can drive that up. I guess current prescribers for Jakafi are both potential myelofibrosis and polycythemia vera prescribers, and obviously that's important to have the polycythemia vera data.

Jim Daly - *Incyte Corporation - EVP and Chief Commercial Officer*

Bret, with respect to MF, I think we're going to keep advancing the ball day by day. The next probably major catalyst for us would be getting some overall survival data reflected in the package insert.

There is a cohort of physicians, quite frankly, who are reluctant to use a product unless they see an overall survival benefit. And I think if we are able to get certain OS data reflected in the label, that should help us expand breadth of prescribing.

With respect to PV, our target audience for PV is about 10,000 physicians. And I think that is going to dramatically increase our overall prescribing base for Jakafi.

Bret Holley - *Guggenheim Securities LLC - Analyst*

Okay, thank you.

Pamela Murphy - *Incyte Corporation - VP of IR and Corporate Communications*

Thank you very much for joining us this morning, and that will conclude the call.

Operator

Ladies and gentlemen, thank you for joining us today. This concludes your teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.
